IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

HARVEY MAHLER, Plaintiff, v. VITAMIN SHOPPE INDUSTRIES, INC. d/b/a THE VITAMIN SHOPPE, Defendant.	Case No. 19-CV-03848 Judge John Robert Blakey

MEMORANDUM OPINION AND ORDER

In this product liability action, Plaintiff Harvey Mahler claims that he developed peripheral neuropathy after taking a multivitamin manufactured by Defendant The Vitamin Shoppe, which, unbeknownst to him, contained arsenic and lead. He sues Defendant for strict liability design defect, manufacturing defect and failure to warn (Counts I–III); negligence (Count IV); breach of implied warranty (Count V); negligent misrepresentation/concealment (Count VI), and violation of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") (Count VII). [26]. Before the Court is Defendant's motion for summary judgment [80] and motions to exclude the opinion and testimony of experts Jon Clark [83], James O'Donnell [84], Octavia Kincaid [85], and Stan Smith [90]. For the reasons explained below, the Court grants Defendant's motion for summary judgment [80] and to exclude James O'Donnell [84] and Octavia Kincaid [85], and denies as moot, the motions as to Jon Clark and Stan Smith [83], [90].

I. Background[1]

On June 25, 2017, Plaintiff Harvey Mahler purchased two bottles of Defendant The Vitamin Shoppe's One Daily Men's 50+ vitamin supplement (the "Vitamin Supplement"). [89] ¶ 1. For the next fifty-one days until August 16, 2017, he took the Vitamin Supplement once per day, according to the directions on the bottle. *Id.* ¶¶ 2–5.

At some point, he began feeling extremely ill and made appointments with various physicians—including with his primary physician, Dr. Andrew, on August 15, 2017; followed by a nephrologist, Dr. Sprague; and a hematologist, Dr. Kaminer. *Id.* ¶¶ 7, 11, 15. Although the parties' briefs do not specify every condition about which he complained, the physicians noted possible peripheral and ulnar neuropathy, bilateral foot numbness, hypertension and renal artery thrombosis. [89] ¶¶ 9–10.

Dr. Andrew, Dr. Sprague and Dr. Kaminer did not tell Plaintiff that the Vitamin Supplement may have caused his symptoms. Nonetheless, Plaintiff sent the Vitamin Supplement to an independent laboratory, Eurofins. [89] ¶ 18. Eurofins sent back a report that showed the Vitamin Supplement contained a detectable amount of arsenic and lead—two types of heavy metals. [100] ¶ 1.[2]

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[1] The Court draws the background facts from the parties' statements of material facts, responses thereto, and cited records. [82]; [89]; [100]. Defendant complains that Plaintiff violated Local Rule 56.1 with respect to his responses to its Statement of Facts, because he: (1) failed to restate the fact to which he responds; (2) merely objects to parts of an asserted fact but remains silent as to other parts; and (3) interjects legal arguments into some responses. [99] at 1–3. As discussed, however, the Court finds Defendant is entitled to summary judgment even considering the purported defects in Plaintiff's responses.

[2] Plaintiff's second amended complaint alleges that Eurofins also reported that the Vitamin Supplement contained a detectable amount of cadmium. [26] ¶¶ 1, 4, 13, 20, 30. Neither Plaintiff's summary judgment response nor the causation experts Plaintiff relies upon, however, suggest that Plaintiff suffered an injury from ingesting cadmium. *See* [87]; [89]. Instead, Plaintiff's summary

None of Plaintiff's treating physicians had, up to that point, diagnosed Plaintiff with possible heavy metal poisoning; nor had they ordered blood tests to screen for heavy metals or found anything that suggested the need for heavy metal screening. [89] ¶¶ 10, 14, 16–17. But Plaintiff, based upon his own research on heavy metal poisoning, believed that the arsenic and/or lead present in the Vitamin Supplement may have caused his symptoms.

Then on June 5, 2018, he visited a neurologist, Dr. Octavia Kincaid. [89] ¶ 21; [82-6] at 14:19–15:8. At his initial visit, he reported that he believed he had peripheral axonal neuropathies related to his feet and left hand ring and pinky fingers. [89] ¶ 22; [82-6] at 15:4–13. He also told her that he had taken vitamins that contained elevated levels of heavy metals and provided her a copy of the Eurofins laboratory report. [89] ¶¶ 22, 28–30.

Dr. Kincaid physically examined Plaintiff and reviewed two electromyography (EMG) tests that another physician had performed on Plaintiff—one on July 17, 2017 and another on April 13, 2018—and which neurologists use to evaluate possible neurological problems.[3] [82-6] at 27:15–28:22; [100] ¶¶ 13–14. Based upon the physical exam and the EMG test results, Dr. Kincaid confirmed that Plaintiff suffered from peripheral neuropathy. [82-6] at 29:8–22. Plaintiff inquired whether arsenic or lead exposure could cause his symptoms, and Dr. Kincaid told him they could,

judgment response makes clear that his claims now rest upon the presence of arsenic and lead, only. *See, e.g.,* [87] at 1–2 (only mentioning lead and arsenic in summarizing opposition to summary judgment); [89] ¶¶ 25 (response), 36 (response); [100] ¶¶ 1, 16.

[3] The parties' statements of material fact do not explain why Plaintiff had an EMG test performed on July 17, 2017 only a few weeks after he started taking the Vitamin Supplement and before he saw his primary physician, Dr. Andrew, on August 15, 2017.

although she would expect a different type of neuropathy from lead poisoning. [82-6] at 30:23–32:9. Dr. Kincaid ordered some basic blood tests (but no heavy metal screening) to rule out a few other more common causes of peripheral neuropathy. The blood tests came back normal, so she clinically diagnosed Plaintiff, based upon Plaintiff's report that he had taken vitamins containing heavy metals, with peripheral neuropathy likely caused from heavy metal toxicity.[4] [100] ¶ 18.

In his second amended complaint [26], Plaintiff alleges that the lead and arsenic contained in the Vitamin Supplement caused his peripheral neuropathy. [26]. He sues Defendant for strict liability and negligent failure to warn, manufacturing defect, and design defect (Counts I–IV); breach of implied warranty (Count V); negligent misrepresentation/concealment (Count VI); and violation of ICFA (Count VII).

Now, pursuant to Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendant moves to exclude the testimony of Plaintiff's four experts—James O'Donnell (causation) [84]; Octavia Kincaid (causation) [85]; Jon Clark (FDA guidelines) [83]; and Stan Smith (damages) [86]. It also seeks summary judgment as to all of Plaintiff's claims, [80].

[4] Plaintiff's second amended complaint alleges that heavy metal toxicity also caused his other symptoms including hypertension and renal artery thrombosis. [26] ¶¶ 1, 3, 36, 53, 59. He has now abandoned these allegations and bases his claims only upon an alleged causal link between the Vitamin Supplement and his peripheral neuropathy. [87].

II. Legal Standards

A. Rule of Evidence 702

Federal Rule of Evidence 702 permits a party to offer expert testimony if the expert has the requisite "knowledge, skill, experience, training, or education" to support the opinion offered and (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

Even if an expert is qualified to offer opinions on a subject, the "expert's ultimate opinion must be grounded in the scientific process and may not be merely a subjective belief or unsupported conjecture." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). Accordingly, courts assume a "gatekeeping role" to ensure that "testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. To determine reliability, courts apply a "flexible" approach that focuses "solely on principles and methodology, not on the conclusions they generate." *Id.* at 594–95. As to evaluating relevance, a court determines whether the proposed expert testimony "logically advances a material aspect of the proposing party's case." *Daubert*, 43 F.3d at 1315. The party seeking to admit the expert testimony bears the burden to establish admissibility under Rule 702. *See Lewis*, 561 F.3d at 705.

B. Summary Judgment

Summary judgment is appropriate where the movant shows through "materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials" that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. In resolving a motion for summary judgment, the court has "one task and one task only: to decide, based on the evidence of record, whether there is any material dispute of fact that requires a trial." *Waldridge v. Am. Hoechst Corp.*, 24 F.3d 918, 920 (7th Cir. 1994) (citations omitted).

To withstand a motion for summary judgment, the nonmovant must "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The Court must construe the record "in the light most favorable to the nonmovant" and avoid the "temptation to decide which party's version of the facts is more likely true." *Payne v. Pauley*, 337 F.3d 767, 770 (7th Cir. 2003). If the evidence is "merely colorable, or is not significantly probative," *Anderson*, 477 U.S. at 249 (citations omitted), or merely raises "some metaphysical doubt as to the material facts," summary judgment may be granted. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

III. Analysis

Federal procedural rules, including the rules of civil procedure and evidence, govern this suit, which comes before the Court on diversity grounds. [26]. But Illinois state law governs Plaintiff's substantive claims and defines the proof Plaintiff must

present to establish the elements of each claim. *See C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015).

Plaintiff's Counts I through IV allege products liability claims based upon strict liability and negligence. [26]. For product liability claims under Illinois law, "whether based on strict liability or negligence, the plaintiff must demonstrate a causal relationship between the injury and the manufacturer's product." *Thornton v. M7 Aerospace LP*, 796 F.3d 757, 770 (7th Cir. 2015). Similarly, Plaintiff's breach of implied warranty (Count V), negligent misrepresentation/concealment (Count VI), and violation of ICFA (Count VII) claims, as alleged, turn on whether any alleged conduct by Defendant proximately caused Plaintiff's alleged injury—his peripheral neuropathy. [26] ¶¶ 84–85 (breach of implied warranty), 99 (negligent misrepresentation), 110 (violation of ICFA); *see also Bd of Educ. of City of Chi. V. A, C and S, Inc.*, 546 N.E.2d 580, 452 (Ill. 1989) (discussing claims for breach of implied warranty and negligent misrepresentation and requirements regarding damages/injury); *De Bouse v. Bayer*, 922 N.E.2d 309, 313 (Ill. 2009) (discussing proximate cause in ICFA).

In addition, when causation "goes beyond the knowledge that the average lay person reasonably could be expected to possess," then a plaintiff must provide proof through "expert testimony." *Muller v. Synthes Corp.*, No. 99-c-1492, 2002 WL 460827, at *6 (N.D. Ill. Mar 26, 2002); *see also Brown v. Baker*, 672 N.E.2d 69, 71 (Ill. App. Ct. 1996) ("Generally, a plaintiff in a personal injury case must present the testimony of a medical expert to establish causation if the relationship between the claimed

injury and the event in question requires special knowledge and training to establish.").

Without dispute, the causation issue in this case—whether the arsenic and/or lead contained in the Vitamin Supplement caused Plaintiff's peripheral neuropathy—requires expert testimony. On this, Plaintiff offers evidence from a retained pharmacist, James O'Donnell, and from his non-retained treating neurologist, Octavia Kincaid. Plaintiff asserts that Dr. O'Donnell's[5] and Dr. Kincaid's testimony both establish general causation, and Dr. Kincaid's testimony also establishes specific causation. [87] at 5, 8–12. General causation examines whether the product at issue "had *the capacity* to cause the harm alleged," while specific causation considers whether the product "did, *in fact*, cause the harm alleged." *C.W. ex rel Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015) (emphasis in original) (internal citations omitted).

In moving for summary judgment on Plaintiff's claims, Defendant primarily argues that while Plaintiff's laboratory tests showed that the Vitamin Supplement contained a detectable amount of arsenic and lead, Plaintiff does not have admissible evidence that the amount of arsenic and/or lead in the Vitamin Supplement either could, or did, cause his alleged peripheral neuropathy. [81]. Specifically, Defendant argues that Plaintiff's only evidence comes from Dr. Kincaid and Dr. O'Donnell, but that neither of them offer expert opinions that meet the standards required for expert

[5] Defendant refers to James O'Donnell as "Mr. O'Donnell" and insists that he "is not a doctor of any kind." [84] at 2. James O'Donnell does hold a Doctor of Pharmacy (*i.e.*, "PharmD") degree [84-1], however, and the Court refers to him as Dr. O'Donnell based upon this degree.

testimony under Rule of Evidence 702 and *Daubert*. Because the Court agrees that Plaintiff cannot survive summary judgment on his claims without these witnesses' causation testimony, the Court begins by evaluating Defendant's motions [84], [85] to exclude their testimony pursuant to Rule 702 and *Daubert*.

A. Defendant's Motion to Exclude Dr. Octavia Kincaid [85]

Dr. Octavia Kincaid is an adult neurologist who specializes in neuromuscular neurology. She holds board certification in adult neurology, clinical neurophysiology, and neuromuscular medicine through the American Board of Psychiatry and Neurology. [85-1] at 9:5–10:22. She is not a retained expert here. Instead, as discussed above, she treated Plaintiff for his peripheral neuropathy beginning in 2018.

Plaintiff relies upon Dr. Octavia Kincaid to establish both general and specific causation—that is, that the lead and arsenic contained in the Vitamin Supplement Plaintiff took could and did cause his peripheral neuropathy. [87] at 8–11. Defendant moves to exclude Dr. Kincaid's opinions for two reasons. First, Defendant argues that Plaintiff failed to properly disclose her as an expert under Federal Rule of Civil Procedure 26(a)(2). [85] at 5–6. Second, Defendant argues that Dr. Kincaid's causation opinions do not meet Rule 702 and *Daubert* reliability requirements because she failed to examine the amount of arsenic and lead that Plaintiff ingested. *Id*. at 6–9.

Regarding disclosure, Rule 26(a)(2) requires that a party disclose "the identity of any witness it may use at trial" to present expert testimony. Fed. R. Civ. P. 26(a)(2)(A). If a disclosed expert witness "is retained or specially employed to provide

expert testimony," then the party must also provide a written expert report. Fed. R. Civ. P. 26(a)(2)(B). For a non-retained expert witness, however, the party does not need to provide a written expert report but does need to disclose (1) the subject-matter of expert testimony and (2) a summary of the facts and opinions to which the witness will testify. Fed. R. Civ. P. 26(a)(2)(C).

Defendant argues that Plaintiff did not properly disclose Dr. Kincaid as a non-retained expert witness under Rule 26(a)(2). [85] at 5–6. Because Dr. Kincaid treated Plaintiff, Defendant acknowledges that Plaintiff may still offer her as a *fact* witness to testify about "her observation, diagnoses, and treatment" but maintains that she may not offer expert opinions regarding causation. *Id.*

In response, Plaintiff insists that he properly disclosed Dr. Kincaid as an expert in his Response to Mandatory Initial Discovery where he disclosed that:

> Dr. Kincaid is a Neurologist who provided medical care to Harvey Mahler from June 5, 2018 to the present. Generally, Dr. Kincaid is expected to testify regarding the medical care she provided to Harvey Mahler (including diagnoses made), her knowledge of the ongoing risks associated with the type of injuries suffered by Harvey Mahler, her knowledge of the recognition, diagnosis, etiology, and treatment of the type of injuries suffered by Harvey Mahler, and any communications she may have had with other medical providers regarding Harvey Mahler. Her testimony is believed to include the information contained in such physicians' medical records.

[91] at 2–3. Plaintiff acknowledges that the above disclosure did not refer to Dr. Kincaid as an "expert," but contends that this disclosure both provides the subject-matter of general and specific causation and provides a summary of the facts and opinions she will offer. *Id.* at 3.

The Court disagrees. Even if the above discovery response sufficiently discloses the subject-matter of causation (which is not evident from the disclosure), nowhere does it provide a summary of the facts and opinions she may offer as to that issue. Therefore, Plaintiff did not properly disclose Dr. Kincaid as an expert under Rule 26(a)(2)(C).[6]

Nonetheless, even if Plaintiff had properly disclosed Dr. Kincaid as an expert witness on specific causation, her deposition testimony confirms that the methods she used to arrive at her opinions do not meet Rule 702 and *Daubert* reliability standards.

As discussed above, Dr. Kincaid first treated Plaintiff on June 5, 2018 and diagnosed him with peripheral neuropathy. [89] ¶ 21; [82-6] at 14:19–15:8. During her deposition, Dr. Kincaid testified that "there's hundreds, if not thousands" of causes for peripheral neuropathy and exposure to things "like heavy metals, and other types of toxic exposures" is "much more rare" than other causes. [85-1] at 13:17–25.

She testified that Plaintiff told her during the initial consultation that he had taken multivitamins that contained heavy metals and that he thought they may be causing his neurological symptoms. *Id.* at 20:1–12, 29:15–25, 38:11–16. She also

[6] Defendant argues that because Plaintiff did not properly disclose Dr. Kincaid as an expert witness, she may offer fact testimony about her neuropathy diagnosis, but may not testify about what caused it. [85] at 5–6. The Seventh Circuit, however, has emphasized that treating physicians may testify about causation to the extent they made those determinations "in the course of providing treatment." *Meyers v. Nat'l R.R. Pass. Corp.*, 619 F.3d 729, 735 (7th Cir. 2010). Thus, to the extent Dr. Kincaid reached causation opinions as part of her treatment, she could testify to those as a fact witness, just not as an expert witness, *provided such evidence was properly disclosed*. The Court need not address this issue further, however, because beyond the disclosure issues, this Court also finds that even if Plaintiff had properly disclosed Dr. Kincaid, her expert testimony on causation remains inadmissible under Rule 702 and *Daubert* based upon the requisite reliability analysis, as explained below.

testified that she ordered some blood tests "to make sure we weren't missing obvious common neuropathies, or treatable neuropathies," but that when those tests came back negative, heavy metal poisoning remained the "possible explanation as backup" and she concluded metal poisoning "was the highly probable cause of" Plaintiff's "peripheral neuropathy."[7] *Id.* at 79:15–80:1, 86:4–14.

She also agreed, however, that heavy metals such as arsenic and lead sometimes appear in various products and there exist "published data from the government saying how much is allowable" in different products. *Id.* at 26:20–25. She further agreed that the amount and length of time that someone consumed a heavy metal remains relevant as to whether it could cause peripheral neuropathy and she "would want to probably review some of the medical literature around those toxins to determine, sort of, is there any known threshold at which patients need to be exposed, in terms of timeline." *Id.* at 76:6–12. Specifically, she testified that, to properly determine potential toxicity levels, she would have to "probably start with some basic medical texts" and "might even go like to the USDA, or to the FDA looking

[7] During her deposition, Dr. Kincaid stated that she diagnosed "heavy metal toxicity" as the "underlying cause" of Plaintiff's peripheral neuropathy, [85-1] at 34:13–14, but she does not state whether she believed that arsenic, lead, or both likely caused his peripheral neuropathy. Elsewhere, however, Dr. Kincaid elaborated that peripheral neuropathy encompasses both axonal neuropathy (neuropathy involving the "axon" or "wire itself of the nerve"), [85-1] at 15:17–20, and demyelinating neuropathy (neuropathy involving "the insulating coating on the outside of the nerve"), *id.* at 31:12–13, and she diagnosed Plaintiff with "length dependent axonal sensory motor neuropathy," [85-1] at 77:9–10. She also testified that even though lead and arsenic might cause peripheral neuropathy, "lead is a known cause of demyelinating neuropathy" whereas arsenic "can cause a sensory neuropathy, which is a little unclear whether that's axonal, or demyelinating, but typically, that would be axonal." *Id.* at 31:25–5. This testimony, therefore, suggests that Dr. Kincaid believes that arsenic, but not lead, likely could have caused Plaintiff's diagnosed axonal peripheral neuropathy. Otherwise, this would suggest a separate problem with the reliability of Dr. Kincaid's causation opinions at least as to lead poisoning.

at governmental levels, because those are usually pretty standardized and have a lot of data behind them." *Id.* at 91:19–24.[8]

Despite this, the record lacks evidence of any such analysis and she testified that she could not recall if (and her notes did not indicate that) she even asked Plaintiff how long he had taken the Vitamin Supplement. She also could not recall if she looked at any reference materials to determine how much or for how long one must consume lead or arsenic to develop peripheral neuropathy. *Id.* at 73:20–74:2. At most, she speculated that she "probably went back and measured, and looked up the references" and she "easily could have looked it up, but I didn't write it down." *Id.* at 88:16–23.

This testimony shows that Plaintiff cannot establish that Dr. Kincaid employed methodologies sufficient to satisfy the *Daubert* reliability requirements. As Defendant correctly points out, courts across the country frequently hold that dosage matters with respect to causation in toxic tort cases. For example, in *Krik v. Crane Co.*, a court excluded a causation expert in an asbestos tort case who held that because he "could not rule out that a single dose of asbestos causes injury," then "any and all exposure to asbestos is necessarily harmful." 76 F. Supp. 3d 747, 752–73 (N.D. Ill. 2014). The court emphasized that such reasoning "is not an acceptable approach for a causation expert to take." *Id.* As another example, in *Cunningham v. Masterwear,*

[8] Defendant's summary judgment motion argues, at length, that the arsenic and lead levels in the Vitamin Supplement fell well below the FDA published acceptable daily intake levels. [81] at 7–10. Defendant invites the Court to take judicial notice of these FDA levels and find that, based upon them, no jury could find that the Vitamin Supplement contained "dangerous levels" of lead. *Id.* The Court declines Defendant's invitation, however, to resolve the claims on this basis.

Inc., a court excluded a causation expert who did not examine level of exposure to a chemical, PCE, because "it is the dose that makes the poison" and it "may be that Plaintiffs were exposed to PCE, but if that dose and duration that they were exposed to is medically insignificant, then it is irrelevant to their condition." No. 04-cv-1616, 2007 WL 1164832, at *5 (S.D. Ind. Apr. 19, 2017). Similarly, in *In re Denture Cream Products Liability Litigation*, a court excluded expert testimony regarding whether copper in denture cream injured the plaintiff after prolonged use because the expert failed to consider "dose-response." 795 F. Supp. 2d 1345, 1351 (S.D. Fla. 2011) (quoting *McClain v. Metabolife, Int'l., Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005)).

Plaintiff insists that Dr. Kincaid's causation opinions remain reliable because she "'probably' (*i.e.*, more likely than not) looked up the lead and arsenic reference levels when she reached her opinion." [91] at 6. Although the "more likely than not" standard may apply to Plaintiff's burden of proof with respect to his claim, Rule 702 and *Daubert* require that a court evaluate reliability based upon what methods an expert used, not what methods an expert "probably" used.

Dr. Kincaid agrees that the dose and duration of exposure remains relevant to whether arsenic or lead can and did cause peripheral neuropathy. Yet, she cannot remember whether she evaluated how much arsenic or lead was in the Vitamin Supplement. She also does not know if she asked Plaintiff how long he took the Vitamin Supplement before she concluded that the heavy metals in the Vitamin Supplement likely caused Plaintiff's peripheral neuropathy.

Of course, the Court offers no opinion on Dr. Kincaid's methods from a clinical or treatment perspective. In fact, Dr. Kincaid herself emphasized that her conclusion was a "clinical diagnosis" based upon the information before her at that time and was not intended to gather "proof" of causation. *Id*. at 32:22–33:8. She also emphasized that she chose not to conduct other tests on Plaintiff or investigate further the Vitamin Supplement "because he already stopped taking the potentially offending agents, it was not cost effective, nor was it going to change my behavior, nor his clinical behavior, in terms of managing his neuropathy to do all those tests, that, perhaps, would satisfy a court of law." *Id*. at 83:15–19.[9]

Overall, regardless of the validity of Dr. Kincaid's methods from a clinical and diagnostic perspective, Plaintiff has failed to show that Dr. Kincaid's causation opinions satisfy *Daubert*'s reliability prong. As such, they remain inadmissible under Rule 702.

B. Motion to Exclude James O'Donnell [84]

Defendant also seeks to exclude Dr. O'Donnell's causation opinions. [84]. James O'Donnell is a pharmacist and Associate Professor of Pharmacology at Rush University Medical Center. [84-1]. He holds a Doctor of Pharmacy degree and a Master of Science in Clinical Nutrition. *Id*. Plaintiff disclosed Dr. O'Donnell as a retained expert and submitted an expert report from him that summarizes nine opinions:

[9] Dr. Kincaid's comments about why she did not investigate further illustrate the risk a plaintiff may take by relying upon a treating physician to establish causation, especially in a toxic tort case involving complex etiologies.

1. I concur with Dr. Kincaid's attribution of Dr. Mahler's toxic neuropathy as being caused by the exposure to the contamination vitamins. Arsenic is well known to cause neuropathies.

2. Toxicology literature provides biologic plausibility support for the diagnosis (general causation). The mechanism of action (MOA) is inhibition of enzyme function leading to segmented demyelination and peripheral neuropathy. Arsenic interferes with enzyme function from sulfhydryl group by binding trivalent Arsenic (As^{3+} or by binding with phosphate. Inorganic As or metabolites may induce oxidative stress, alter gene expression, and interfere with cell signal transduction. Cellular mitochondria accumulate arsenic, and respiration mediated y [*sic*] NAD-linked substrates is particularly sensitive to arsenic (*Cassaret & Doull's*). Similar mechanisms of action are described for lead.

3. The vitamin product purchased and consumed by Dr. Mahler tested positive for arsenic. Hair and nails tested below the levels of detection. This does not rule out As and Cd in Dr. Mahler's biologic samples.

4. There was *notice* of widespread heavy metals contamination of dietary supplements, particularly by raw materials sourced in China and India.

5. Vitamin Shoppe/Nutriforce knew or should have known widespread contamination from raw material sources, especially China and India. Indeed, Mr. Morrison testified that he was aware of the widespread contamination.

6. Vitamin Shoppe/Nutriforce should have tested raw materials received and final testing of manufactured product for presence of toxic heavy metals, including As and Cd. A reasonable prudent dietary supplement manufacturer would have tested, given the known contamination. Reliance on raw materials suppliers from notoriously contaminated sources should have prompted this testing.

7. DSHEA / FDA requirements are minimal standards. Manufacturers are not limited to (minimal) requirements. There are prohibitions on adulterated or contaminated products. The knowledge of known contamination/risks would require testing.

8. Vitamin Shoppe/Nutriforce only tested for lead (known adulterants). Vitamin Shoppe/Nutriforce did not test for As (arsenic) and Cd (cadmium). Vitamin Shoppe/Nutriforce was uncertain on the content and extent of testing; instead relied on raw material suppliers on testing and isolation of heavy metals in the raw materials.

9. Vitamin Shoppe/Nutriforce should have warned consumers of the risk of heavy metal contamination in their vitamins, and the risks associated with such contamination.

[84-1] at 3–4.

Defendant argues that Dr. O'Donnell lacks the qualifications to offer some of these opinions. It also argues that his opinions regarding raw ingredients remain irrelevant. Finally, he argues that Dr. O'Donnell failed to employ a reliable (or any) methodology to reach his general causation opinions about the Vitamin Supplement. Specifically, Defendant complains that, just like Dr. Kincaid, Dr. O'Donnell failed to consider the amount of arsenic or lead that someone would need to ingest to cause neuropathy. Defendant also argues that Dr. O'Donnell makes factual assumptions that the record does not support.

The Court agrees that Dr. O'Donnell's causation opinions raise multiple reliability problems that render them inadmissible under Rule 702 and *Daubert*. Although Dr. O'Donnell's expert report summarized his causation opinions, he explained in his deposition the logic and methods that he used to reach those opinions. These explanations illustrate the reliability problems that render his opinions both unreliable and irrelevant.

Namely, he first stated, based upon his experience and training in chemistry, that arsenic and lead are injurious to health, generally. [84-2] at 60:7–9. He also opined that, from a chemical perspective, arsenic and lead can cause neuropathies. *Id*. at 58:2–59:1. Second, based upon his review of the records, he opined that Plaintiff took "this product for at least four years." *Id*. at 60:12–13. Third, he opined that the Vitamin Supplement that Plaintiff consumed from June 2017 to August 2017

contained detectable amounts of lead and arsenic. *Id.* at 69:12–16. Fourth, he assumed that all the vitamins Plaintiff took over four years contained lead and arsenic even though only the Vitamin Supplement purchased in June 2017 was tested. *Id.* at 50:19–52:12. He made this assumption because the tested Vitamin Supplement contained it, and because the raw materials that Defendant used in its vitamins came from China and reports about other products made from raw materials from China showed those products contained lead and/or arsenic. *Id.* Fifth, he opined that Plaintiff must have taken vitamins containing enough lead and arsenic cumulatively to cause neuropathy because Dr. Kincaid diagnosed Plaintiff with neuropathy caused by heavy metal poisoning.

These opinions include numerous assumptions not supported by the record, unreliable speculation, and circular reasoning. To begin, Dr. O'Donnell's causation opinion rests upon his belief that Plaintiff took the Vitamin Supplement for at least four years. [84-2] at 60:10–13 ("I identify that arsenic is injurious to health. Identified – have expressed, based on the review of the records, that he had taken this product for at least four years."). But the record fails to provide support for this assumption. Instead, the parties agree that Plaintiff purchased two bottles of the Vitamin Supplement on June 25, 2017 and he took one tablet per day from June 25, 2017 through August 16, 2017. [82] ¶¶ 1–5; [89] ¶¶ 1–5. Plaintiff himself only asserts that he "was exposed to arsenic in the vitamin supplements for approximately fifty-

one days." [89] ¶ 36 (response).[10] In other words, the parties agree that Plaintiff took the Vitamin Supplement for fifty-one days, not four years.

Next, even if Plaintiff took vitamin supplements manufactured by Defendant for years, the record fails to establish whether other vitamins purchased before June 25, 2017 ever contained arsenic or lead and, if so, how much. Yet, Dr. O'Donnell *assumes* that they contained lead and arsenic because Defendant sourced raw materials from China, and "reports" during that time found that other products—including multivitamins and baby food—manufactured by other companies contained arsenic, lead and other heavy metals. [84-2] at 86:2–6 ("I'm making an assumption. I'm giving an expert opinion that it did based on the fact that there's been a widespread contamination reported of raw materials for dietary supplements, particularly supplements sourced in China and India."). Just because products manufactured by other companies used materials from China and contained lead and arsenic does not support the assumption that Defendant's products contained toxic levels of lead and arsenic. Dr. O'Donnell's opinion on this constitutes rank speculation. It simply does not meet the *Daubert* reliability threshold.[11] *See Lewis*

[10] Plaintiff testified at his deposition that he had taken vitamins for a number of years prior to June 2017 and that he sometimes purchased these vitamins from Defendant's store. [82-1] at 36:3–13, 39:23–42:10. But he did not know if he had taken the same type of vitamin as the Vitamin Supplement here. He also testified that he may have taken a vitamin from Sam's Club at some point. Despite this equivocal testimony, Plaintiff does not present evidence (or argue, other than through Dr. O'Donnell's opinion) that he took the relevant Vitamin Supplement prior to June 25, 2017.

[11] Dr. O'Donnell's unsupported beliefs that Plaintiff took vitamins containing toxic levels of lead and arsenic for four years is material because he testified that he's "considering cumulative exposure," [84-2] at 56:20–57:3, and "chronic toxicity from a heavy metal is much more toxic than an – an acute exposure to the same heavy metal," *id*. at 37:5–7. Thus, even putting aside the reliability issue the Court discusses below, this renders Dr. O'Donnell's general causation opinions irrelevant given that the record only shows that Plaintiff was exposed to the Vitamin Supplement for fifty-one days, not

v. CITGO Petroleum Corp., 561 F.3d at 705 (holding that an "expert's ultimate opinion must be grounded in the scientific process and may not be merely a subjective belief or unsupported conjecture").

Yet, even if one accepts that Plaintiff took vitamins for years that contained some arsenic and lead, Dr. O'Donnell's causation opinions also lack reliability because, like Dr. Kincaid, Dr. O'Donnell fails to consider, or account for, dosage in any reliable manner. To begin, as mentioned above, Dr. O'Donnell agrees, generally, that "the dose response relationship for toxicity differs between an acute dose" and "chronic toxicity." *Id.* at 36:2–5. Dr. O'Donnell also agreed that there exist "acceptable daily intake levels" of heavy metals under which one would not expect to find toxic exposure. [84-2] at 85:4–11. He also agreed that, even for chronic exposure, the scientific community believes "that there's not gonna be chronic toxicity if it's in an acceptable level." *Id.* at 85:9–11. Yet, Dr. O'Donnell agrees that he offers no opinion about the "dose response relationship between" arsenic or lead "and any medical condition complained of by" Plaintiff. [84-2] at 33:24–34:2, 34:8–11.

To justify this, Dr. O'Donnell—and Plaintiff, in his response—points to a 2001 toxicology textbook, *Casarett and Doull's Toxicology: The Basic Science of Poisons*, which states that "it is difficult to establish a dose response relationship of heavy metal toxicity." [84-2] at 41:20–21; [93] at 7. In other words, Dr. O'Donnell (and Plaintiff) suggests that, because it may be difficult to establish a dose-response relationship, Dr. O'Donnell can opine about causation without considering dose-

four years. *Daubert*, 43 F.3d at 1315 (holding that expert testimony is only relevant if it "logically advances a material aspect of the proposing party's case.").

response relationships at all. Plaintiff cites no caselaw to support this proposition. Further, even if it remains difficult to establish a relationship, Dr. O'Donnell agrees that literature still discusses dose-response rate and there exist "acceptable daily intake levels" for heavy metals like arsenic and lead. Yet, he fails to analyze or even discuss potential thresholds (for either acute or cumulative exposure). He also fails to acknowledge "acceptable daily intake levels" or consider whether the levels found in the Vitamin Supplement fell within those reported levels.

Instead, he testified that he used the following process to reach his conclusions. He explained that "all of" his "opinions are connected to those of Dr. Kincaid," [84-2] at 62:16–17, and that he concluded the Vitamin Supplement contained enough arsenic to injure someone because:

> I identified that arsenic is injurious to health. Identified – have expressed, based on the review of the records, that he had taken this product for at least four years. The – I have identified that establishing a dose response relationship is difficult. I've identified that Dr. Kincaid has a clinical diagnosis of heavy metal induced neuropathy, ruling out other causes.

[84-2] at 60:10–17. Similarly, with respect to lead (and arsenic, again), he stated that even though he did not consider dosage, and even though the medical community believes "that there's not gonna be chronic toxicity" when someone consumes below the acceptable daily intake levels, he still finds causation here, because "we have a patient here who developed neuropathy" and we "know that his vitamins contained arsenic, and lead." *Id.* at 85:11–13. In other words, Dr. O'Donnell reasons that because Dr. Kincaid diagnosed Plaintiff with heavy metal-induced neuropathy and because the Vitamin Supplement that Plaintiff took contained lead and arsenic, then

the Vitamin Supplement must have contained enough lead and/or arsenic to cause neuropathy.

The logical flaws to Dr. O'Donnell's chain of reasoning are striking and make clear that Dr. O'Donnell employed no reliable methodology to reach his causation opinion. Instead, he assumed that the amount of lead and arsenic contained in the Vitamin Supplement must be enough to cause neuropathy because Plaintiff developed neuropathy. Such reasoning does not even remotely suggest reliability or satisfy *Daubert*. Accordingly, Dr. O'Donnell's causation opinions remain inadmissible under Rule 702.

As a final note, because the Court excludes Dr. O'Donnell's causation opinions based upon reliability, the Court does not consider Defendant's other argument that Dr. O'Donnell lacks the qualifications to opine on causation. Further, as discussed, Plaintiff's claims do not survive summary judgment without admissible evidence of causation and the Court has now excluded the only evidence he offers on causation. Accordingly, the Court need not to consider the admissibility or reliability of Dr. O'Donnell's opinions that do not relate to causation, such as the adequacy of the Vitamin Supplement's warnings.

C. Motion for Summary Judgment [80]

As set out above, Plaintiff's claims all require that he establish, by a preponderance of the evidence, that the heavy metals in the Vitamin Supplement caused his neuropathy. Plaintiff relies upon Dr. Kincaid and Dr. O'Donnell to establish a triable issue on this critical element of his claims. *See* [87], [89]. With

their testimony excluded under Rule 702, Plaintiff has no other source of evidence to plausibly meet his burden. Accordingly, the Court grants summary judgment in Defendant's favor on Counts I–VII.

Further, having found that Plaintiff cannot survive summary judgment as to any of his claims, the Court denies as moot Defendant's motions to bar expert testimony of Jon Clark [83] and Stan Smith [86]. It also declines to consider Defendant's alternative argument regarding preemption as to Counts VI and VII.

IV. Conclusion

For the reasons explained above, the Court grants Defendant's Motion to Bar Plaintiff's Expert Witness Octavia Kincaid [85], and grants Defendant's Motion to Bar Plaintiff's Expert Witness James T. O'Donnell [84] as to his causation opinions but otherwise denies the motion [84] as moot. The Court also grants Defendant's Motion for Summary Judgment [80] as to all counts. Finally, it denies as moot Defendant's Motion to Bar Plaintiff's Expert Witness Jon Clark [83] and Defendant's Motion to Bar Plaintiff's Expert Witness Stan Smith [86]. Civil case terminated.

Dated: September 20, 2023

Entered:

John Robert Blakey
United States District Judge